



UNITED STATES ENVIRONMENTAL PROTECTION
AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

November 14, 2015

MEMORANDUM

Subject: Efficacy Review for EcaFlo® Anolyte
EPA Reg. No. 82341-1
DB Barcode: D428914

From: Son Nguyen
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Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
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To: Demson Fuller RM32/Srinivas Gowda
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: I.E.T., Inc.
4235 Commerce St.
Little River, SC 29566

Formulation from the Label:

<u>Active Ingredient(s)</u>	% by wt.
Hypochlorous Acid	0.046%
<u>Other Ingredients</u>	<u>99.954%</u>
Total	100.00%

I. BACKGROUND

The product, EcaFlo® Anolyte (EPA Reg. No. 82341-1), is an EPA-approved one-step disinfectant (bactericide, virucide) on hard, non-porous surfaces in hospitals, home health care settings, nursing homes, dental facilities, laboratories, food processing and service establishments veterinary clinics, and other institutional and commercial facilities. The applicant requested to amend the registration of this product to update the master table and to add new claims of effectiveness as a disinfectant against Adenovirus, Enterovirus 68, Norovirus, Poliovirus, Rhinovirus, Rotavirus, and Respiratory Syncytial Virus. Additionally, the applicant is requesting for a reconsideration of the *Candida albicans* claim using previous study (MRID 489928-10). Efficacy studies were conducted at Antimicrobial Test Laboratories, located at 1304 W. Industrial Blvd. Round Rock, Texas 78681.

The data package contains a letter from the applicant to EPA (dated July 21, 2015), EPA form 8570-1 (Application for Pesticide Registration), EPA form 8570-34 (Certification with Respect to Citation Data), EPA Form 8570-35 (Data Matrix), 7 efficacy studies (MRID Nos. 49680701 through 49680707), and the proposed label. Statements of No Data Confidentiality Claims, Good Laboratory Practice Statements and Quality Assurance Statements were included with each study.

II. USE DIRECTIONS

The product, EcaFlo® Anolyte, is designed for disinfecting and sanitizing hard, non-porous surfaces. The proposed label indicates that the product may be used as a disinfectant or sanitizer on pre-cleaned, hard, non-porous surfaces. Directions on the proposed label provide the following information regarding use of the product.

To [Clean and] Disinfect [and Deodorize] Hard, Non-Porous Surfaces:

For heavily soiled areas, a preliminary cleaning is required. Apply [Wipe, Spray or Drip] EcaFlo® Anolyte at 500 ppm FAC to hard, non-porous surfaces with a cloth, wipe, mop or sponge. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry. This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection.

To [Clean and] Disinfect Water Sensitive [Electronic] Equipment, Hard, Non-Porous Surfaces:

Completely power off electrical equipment prior to treatment. Pre-clean soils from external surfaces to be disinfected with a clean paper towel, cloth, microfiber, or sponge, which may be dry or slightly wetted with this product. Carefully apply [Anolyte] [this product] using a cloth or spray device so that only enough solution is applied to keep the surface thoroughly wet for 10 minutes. Avoid over soaking and prevent pooled or puddled areas. Treated surfaces must remain wet for 10 minutes. Reapply as necessary to keep wet for 10 minutes. Do not rinse. Allow surfaces to air dry. If hazy film or streaks appear after 10 minutes, wipe clean with a dry or slightly damp clean paper towel, cloth, or microfiber. Do not restore power to electronic equipment until thoroughly dry.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Virucides:

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method

(for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant at LCL must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Disinfectants for Use on Hard Surface Environments (Additional Microorganisms):

Effectiveness of disinfectants against specific bacteria other than those named in the designated test microorganism(s) is permitted, provided that the target microbe is likely to be present in or on the recommended use areas and surfaces. This section addresses efficacy testing for limited, broad-spectrum or hospital disinfectants which bear label claims against bacteria other than *S. enterica* (ATCC10708), *S. aureus* (ATCC 6538) or *P. aeruginosa* (ATCC 15442). The effectiveness of disinfectant against specific bacteria must be determined by AOAC Use-Dilution Method (UDM). Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. The product should kill all the test microorganisms on all carriers in ten minutes. The minimum carrier count to make the test valid should be 1×10^4 CFU/carrier. For a valid test, no contamination of any carrier is allowed.

Supplemental Claims:

An antimicrobial agent identified as a “one-step” disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacterial, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same tolerance level.

IV. SYNOPSIS OF SUBMITTED EFFICACY STUDY

The active ingredient concentrations of Batch 1/2/2015-1 and Batch 1/2/2015-2 were both reported to be **409ppm HOCl (415 ppm FAC)**, Batch 2/3/2015-1 was reported to be **405ppm HOCl (416 ppm FAC)**, and Batch 2/3/2015-2 was reported to be **408ppm HOCl (418 ppm FAC)**. From the 11/13/12 Submission, Batch 5/30/2012-1 and Batch 5/30/2012-2 were reported to be **410ppm HOCl**. All batches meet EPA's criteria for efficacy testing, as detailed in the Agency's guidance document “Lower Certified Limit Testing Guidance”. The active ingredient is below the lower certified limit (as specified in the Confidential Statement of Formula).

- 1. MRID 49680701 “Virucidal Efficacy of a Disinfectant for Use on Nonporous, Inanimate Surfaces – Adenovirus 1, Strain Adenoid 71”, Test Organism: Adenovirus 1, Strain Adenoid 71, ATCC VR-1 for EcaFlo® Anolyte, by Erika Guin, B.S. Study conducted at Antimicrobial Test Laboratories. Study completion date – May 21, 2015. Study Identification No. GLP1254.**

This study was conducted against Adenovirus 1, Strain Adenoid 71, ATCC VR-1, using MRC-5 (ATCC CCL-171) as the host cell line. Two batches (3-2-2015-1 and 3-2-2015-2) of the product, EcaFlo® Anolyte, EPA Reg. No. 82341-1, were tested using Protocol No. P1284 (copy provided). The product was received ready to use. Five (5) percent fetal bovine serum was added to the prepared culture to achieve a 5% organic soil load. Two glass petri dishes (one per lot) were

inoculated with 0.20 mL of the prepared virus test inoculum (supplemented by the organic soil load) and spread over the entire area. The viral inoculum is allowed to dry for 6 minutes, or until visibly dry, at 26.6-26.7°C and at 22-23% relative humidity. Each contaminated and dried carrier was treated by pipette delivery of 2.0 mL of the test substance. The carriers are gently rotated to ensure complete coverage of the test substance over the entirety of each test surface. The carriers were exposed for 10 minutes \pm 5 seconds at 26.7°C. After the contact time, sterile cell scrapers are used to mechanically detach the virus films from the glass Petri dish carriers. The suspensions are promptly pipetted into pre-equilibrated Sephacryl (S-1000 SF) Gel Filtration Columns (phosphate-buffered saline [PBS] supplemented with 0.5% fetal bovine serum) for test substance neutralization. The filtrates (10^{-1} dilution) were then tittered by 10-fold serial dilution and applied in quadruplicate per dilution to the host cell culture monolayers prepared to suitable confluency in multi-well trays. All assay trays were incubated at 37 \pm 2°C (5 \pm 1% CO₂), for a minimum of 30 minutes to facilitate virus-host cell adsorption. Each well then received ~1.0mL of the test/cell culture medium (EMEM supplemented with 2% (v/v) fetal bovine serum (FBS) plus antibiotics [100 μ g/mL Kanamycin, 100 units/mL penicillin G, 100 μ g/mL Streptomycin, and 0.25 μ g/mL amphotericin B]) via pipette delivery. The cell culture assay trays were incubated at 37 \pm 2°C for 7 days in a humidified atmosphere of 5 \pm 1% CO₂ and examined regularly for the presence or absence of unspecified cytopathic effects, cytotoxicity, and contamination. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. Controls included those for cell culture control, cytotoxicity, dried virus plate recovery, and neutralization. The dried virus plate recovery titer obtained for Adenovirus 1, Strain Adenoid 71, ATCC VR-1 was **5.55 log₁₀ TCID₅₀** per carrier. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥ 3.75 log₁₀** for both batches.

Note: A deviation from the approved protocol occurred on 19 FEB 2015 wherein the EcaFlo Anolyte test substance (Lot: 3-2-2015-1; Lot: 3-2-2015-2) was tested while at an active concentration below that listed within the approved protocol (410 ppm). Test Substance Lots 3-2-2015-1 and 3-2-2015-2 were diluted by the Study Sponsor on 02 MAR 2015 to the active ingredients of 405 ppm and 408 ppm HOCl, respectively. It is the decision of the Study Director that this deviation did not impact the integrity or validity of the study as evidenced by the deviating concentrations falling below the level dictated by the protocol, rather than above.

A deviation from the approved protocol occurred on 06 MAR 2015 wherein the Sephacryl S-1000 Gel Filtration Column used to neutralize and harvest the EcaFlo Anolyte test substance (Lot 3-2-2015-1) slipped during the centrifugation process, preventing the collection of elute. The column was run second time through the centrifuge on 06 MAR 2015 under the following conditions: 1000 x g for 3 minutes at 4°C.

It is the decision of the Study Director that these deviations do not impact the integrity or validity of the study.

- 2. MRID 49680702 “Virucidal Efficacy of a Disinfectant for Use on Nonporous, Inanimate Surfaces – Enterovirus 68, Strain Fermon”, Test Organism: Enterovirus 68, Strain Fermon, ATCC VR-561 for EcaFlo® Anolyte, by Erika Guin, B.S. Study conducted at Antimicrobial Test Laboratories. Study completion date – May 11, 2015. Study Identification No. GLP1257.**

This study was conducted against Enterovirus 68, Strain Fermon, ATCC VR-561, using Vero (ATCC CCL-81) as the host cell line. Two batches (1-2-2015-1 and 1-2-2015-2) of the product, EcaFlo® Anolyte, EPA Reg. No. 82341-1, were tested using Protocol No. P1287 (copy provided). The product was received ready to use. Five (5) percent fetal bovine serum was added to the

prepared culture to achieve a 5% organic soil load. Four glass petri dishes (two per lot) were inoculated with 0.20 mL of the prepared virus test inoculum (supplemented by the organic soil load) and spread over the entire area. The viral inoculum is allowed to dry for 8 minutes, or until visibly dry, at 27°C and at 31% relative humidity. Each contaminated and dried carrier was treated by pipette delivery of 2.0 mL of the test substance. The carriers are gently rotated to ensure complete coverage of the test substance over the entirety of each test surface. The carriers were exposed for 10 minutes \pm 5 seconds at 27.0-27.2°C. After the contact time, sterile cell scrapers are used to mechanically detach the virus films from the glass Petri dish carriers. The suspensions are promptly pipetted into pre-equilibrated Sephacryl (S-1000 SF) Gel Filtration Columns (phosphate-buffered saline [PBS] supplemented with 0.5% fetal bovine serum) for test substance neutralization. The filtrates (10^{-1} dilution) were then tittered by 10-fold serial dilution and applied in quadruplicate per dilution to the host cell culture monolayers prepared to suitable confluency in multi-well trays. All assay trays were incubated at 34 \pm 2°C (5 \pm 1% CO₂), for a minimum of 30 minutes to facilitate virus-host cell adsorption. Each well then received ~1.0mL of the test/cell culture medium (EMEM supplemented with 2% (v/v) fetal bovine serum (FBS) plus antibiotics [100 μ g/mL Kanamycin, 100 units/mL penicillin G, 100 μ g/mL Streptomycin, and 0.25 μ g/mL amphotericin B]) via pipette delivery. The cell culture assay trays were incubated at 34 \pm 2°C for 7 days in a humidified atmosphere of 5 \pm 1% CO₂ and examined regularly for the presence or absence of unspecified cytopathic effects, cytotoxicity, and contamination. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. Controls included those for cell culture control, cytotoxicity, dried virus plate recovery, and neutralization. The dried virus plate recovery titer obtained for Human Enterovirus 68, Strain Fermon, ATCC VR-561 was **4.55 log₁₀ TCID₅₀** per carrier. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥ 2.75 log₁₀** for both batches.

Note: Protocol was amended on 20 FEB 2015 to change the test substance expiration date from 01 FEB 2015 to 15 MAR 2015. This expiration date modification regards the date of manufacture as the date of test substance titration to the lower certifiable limit, and presents an expiration date at 30 days past the new date of manufacture.

A deviation from the approved protocol occurred on 19 FEB 2015 wherein the EcaFlo Analyte test substance (Lot: 1-2-2015-1; Lot: 1-2-2015-2) was tested while at an active concentration below that listed within the approved protocol (410ppm HOCl). Test Substance Lots 1-2-2015-1 and 1-2-2015-2 were diluted by the Study Sponsor on 16 FEB 2015 to an active concentration of 409ppm HOCl.

Another deviation occurred on 19 FEB 2015 when the Sephacryl 2-1000 Super Fine Gel Column containing the harvested Plate Recovery Control and treated viral film for test substance lot 1-2-2015-1 for testing against Human Enterovirus 68, Strain Fermon, ATCC VR-561 were run two times through the centrifuge. The second centrifuge exposure was necessitated by the slippage of the columns into the elute during the initial run. This slippage prevented the full column of elute from being recovered from the columns. The second centrifuge exposure occurred on 19, Feb. 2015 at approximately 1402. The conditions of exposure were: 1000 x g for 3 minutes at 4°C.

According to the Study Director, these deviations did not impact the integrity or validity of the study.

3. MRID 49680703 “Virucidal Efficacy of a Disinfectant for Use on Nonporous, Inanimate Surfaces – Feline Calicivirus, Strain F-9”, Test Organism: Feline calicivirus, Strain F-9, ATCC VR-782 for EcaFlo® Anolyte, by Erika Guin, B.S. Study conducted at Antimicrobial Test Laboratories. Study completion date – May 01, 2015. Study Identification No. GLP1252.

This study was conducted against Feline calicivirus, Strain F-9, ATCC VR-782, using CRFK (ATCC CCL-94) as the host cell line. Two batches (1-2-2015-1 and 1-2-2015-2) of the product, EcaFlo® Anolyte, EPA Reg. No. 82341-1, were tested using Protocol No. P1282 (copy provided). The product was received ready to use. Five (5) percent fetal bovine serum was added to the prepared culture to achieve a 5% organic soil load. Four glass petri dishes (two per lot) were inoculated with 0.20 mL of the prepared virus test inoculum (supplemented by the organic soil load) and spread over the entire area. The viral inoculum is allowed to dry for 12 minutes, or until visibly dry, at 24.6-25.8°C and at 46-47% relative humidity. Each contaminated and dried carrier was treated by pipette delivery of 2.0 mL of the test substance. The carriers are gently rotated to ensure complete coverage of the test substance over the entirety of each test surface. The carriers were exposed for 10 minutes \pm 5 seconds at 25.8-26.7°C. After the contact time, sterile cell scrapers are used to mechanically detach the virus films from the glass Petri dish carriers. The suspensions are promptly pipetted into pre-equilibrated Sephacryl (S-1000 SF) Gel Filtration Columns (phosphate-buffered saline [PBS] supplemented with 0.5% fetal bovine serum) for test substance neutralization. The filtrates (10^{-1} dilution) were then tittered by 10-fold serial dilution and applied in quadruplicate per dilution to the host cell culture monolayers prepared to suitable confluency in multi-well trays. All assay trays were incubated at 37 \pm 2°C (5 \pm 1% CO₂), for a minimum of 30 minutes to facilitate virus-host cell adsorption. Each well then received ~1.0mL of the test/cell culture medium (EMEM supplemented with 2% (v/v) fetal bovine serum (FBS) plus antibiotics [100 μ g/mL Kanamycin, 100 units/mL penicillin G, 100 μ g/mL Streptomycin, and 0.25 μ g/mL amphotericin B]) via pipette delivery. The cell culture assay trays were incubated at 37 \pm 2°C for 7 days in a humidified atmosphere of 5 \pm 1% CO₂ and examined regularly for the presence or absence of unspecified cytopathic effects, cytotoxicity, and contamination. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. Controls included those for cell culture control, cytotoxicity, dried virus plate recovery, and neutralization. The dried virus plate recovery titer obtained for Feline calicivirus, Strain F-9, ATCC VR-782 was **4.80 log₁₀ TCID₅₀** per carrier. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **\geq 3.00 log₁₀** for both batches.

Note: Protocol was amended on 20 FEB 2015 to change the test substance expiration date from 01 FEB 2015 to 15 MAR 2015. This expiration date modification regards the date of manufacture as the date of test substance titration to the lower certified limit, and presents an expiration date at 30 days past the new date of manufacture.

A deviation from the approved protocol occurred on 20 FEB 2015 wherein the EcaFlo Anolyte test substance (Lot: 1-2-2015-1; Lot: 1-2-2015-2) was tested while at an active concentration below that listed within the approved protocol (410ppm HOCl). Test Substance Lots 1-2-2015-1 and 1-2-2015-2 were diluted by the Study Sponsor on 16 FEB 2015 to an active concentration of 409ppm HOCl.

Another deviation from the approved standard operating procedure (TFO 007.1- “Virucidal Efficacy Assay”) occurred on 20 FEB 2015 wherein one well of the 10^{-1} dilution of the Neutralization Effectiveness Control for EcaFlo Anolyte (Lot: 102-2015-1) was seeded with a volume less than that outlined in the S.O.P. (0.1 mL). Approximately 0.05 mL was applied to the well in question.

According to the Study Director, these deviations did not impact the integrity or validity of the study.

- 4. MRID 49680704 “Virucidal Efficacy of a Disinfectant for Use on Nonporous, Inanimate Surfaces – Human Respiratory Syncytial Virus, Strain A-2”, Test Organism: Human Respiratory Syncytial Virus, Strain A-2, ATCC VR-1540 for EcaFlo® Anolyte, by Erika Guin, B.S. Study conducted at Antimicrobial Test Laboratories. Study completion date – May 11, 2015. Study Identification No. GLP1259.**

This study was conducted against Human Respiratory Syncytial Virus, Strain A-2, ATCC VR-1540, using MRC-5 (ATCC CCL-171) as the host cell line. Two batches (1-2-2015-1 and 1-2-2015-2) of the product, EcaFlo® Anolyte, EPA Reg. No. 82341-1, were tested using Protocol No. P1289 (copy provided). The product was received ready to use. Five (5) percent fetal bovine serum was added to the prepared culture to achieve a 5% organic soil load. Two glass petri dishes (one per lot) were inoculated with 0.20 mL of the prepared virus test inoculum (supplemented by the organic soil load) and spread over the entire area. The viral inoculum is allowed to dry for 59 minutes, or until visibly dry, at 7.8-8.7°C and at 37-47% relative humidity. Each contaminated and dried carrier was treated by pipette delivery of 2.0 mL of the test substance. The carriers are gently rotated to ensure complete coverage of the test substance over the entirety of each test surface. The carriers were exposed for 10 minutes \pm 5 seconds at 27.0-27.4°C. After the contact time, sterile cell scrapers are used to mechanically detach the virus films from the glass Petri dish carriers. The suspensions are promptly pipetted into pre-equilibrated Sephacryl (S-1000 SF) Gel Filtration Columns (phosphate-buffered saline [PBS] supplemented with 0.5% fetal bovine serum) for test substance neutralization. The filtrates (10^{-1} dilution) were then tittered by 10-fold serial dilution and applied in quadruplicate per dilution to the host cell culture monolayers prepared to suitable confluency in multi-well trays. All assay trays were incubated at 37 \pm 2°C (5 \pm 1% CO₂), for a minimum of 30 minutes to facilitate virus-host cell adsorption. Each well then received ~1.0mL of the test/cell culture medium (EMEM supplemented with 2% (v/v) fetal bovine serum (FBS) plus antibiotics [100 μ g/mL Kanamycin, 100 units/mL penicillin G, 100 μ g/mL Streptomycin, and 0.25 μ g/mL amphotericin B]) via pipette delivery. The cell culture assay trays were incubated at 37 \pm 2°C for 7 days in a humidified atmosphere of 5 \pm 1% CO₂ and examined regularly for the presence or absence of unspecified cytopathic effects, cytotoxicity, and contamination. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. Controls included those for cell culture control, cytotoxicity, dried virus plate recovery, and neutralization. The dried virus plate recovery titer obtained for Human Respiratory Syncytial Virus, Strain A-2, ATCC VR-1540 was **5.30 log₁₀ TCID₅₀** per carrier. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥ 3.50 log₁₀** for both batches.

Note: A deviation from the approved protocol occurred on 27 FEB 2015 wherein the EcaFlo Anolyte test substance (Lot: 1-2-2015-1; Lot: 1-2-2015-2) was tested while at an active concentration below that listed within the approved protocol (410 ppm HOCl). Test Substance Lots 1-2-2015-1 and 1-2-2015-2 were diluted by the Study Sponsor to an active concentration of 409ppm HOCl. It is the decision of the Study Director that this deviation did not impact the integrity or validity of the study as evidenced by the deviating concentrations falling below the level dictated by the protocol, rather than above.

- 5. MRID 49680705 “Virucidal Efficacy of a Disinfectant for Use on Nonporous, Inanimate Surfaces – Poliovirus 1, Strain Chat”, Test Organism: Poliovirus 1, Strain Chat, ATCC VR-1562 for EcaFlo® Anolyte, by Erika Guin, B.S. Study conducted at Antimicrobial Test Laboratories. Study completion date – May 11, 2015. Study Identification No. GLP1255.**

This study was conducted against Poliovirus 1, Strain Chat, ATCC VR-1562, using Vero (ATCC CCL-81) as the host cell line. Two batches (1-2-2015-1 and 1-2-2015-2) of the product, EcaFlo® Anolyte, EPA Reg. No. 82341-1, were tested using Protocol No. P1285 (copy provided). The product was received ready to use. Five (5) percent fetal bovine serum was added to the prepared culture to achieve a 5% organic soil load. Two glass petri dishes (one per lot) were inoculated with 0.20 mL of the prepared virus test inoculum (supplemented by the organic soil load) and spread over the entire area. The viral inoculum is allowed to dry for 57 minutes, or until visibly dry, at 13.5-26.0°C and at 26-35% relative humidity. Each contaminated and dried carrier was treated by pipette delivery of 2.0 mL of the test substance. The carriers are gently rotated to ensure complete coverage of the test substance over the entirety of each test surface. The carriers were exposed for 10 minutes \pm 5 seconds at 22.2-25.4°C. After the contact time, sterile cell scrapers are used to mechanically detach the virus films from the glass Petri dish carriers. The suspensions are promptly pipetted into pre-equilibrated Sephacryl (S-1000 SF) Gel Filtration Columns (phosphate-buffered saline [PBS] supplemented with 0.5% fetal bovine serum) for test substance neutralization. The filtrates (10^{-1} dilution) were then tittered by 10-fold serial dilution and applied in quadruplicate per dilution to the host cell culture monolayers prepared to suitable confluency in multi-well trays. All assay trays were incubated at 37 \pm 2°C (5 \pm 1% CO₂), for a minimum of 30 minutes to facilitate virus-host cell adsorption. Each well then received ~1.0mL of the test/cell culture medium (EMEM supplemented with 2% (v/v) fetal bovine serum (FBS) plus antibiotics [100 μ g/mL Kanamycin, 100 units/mL penicillin G, 100 μ g/mL Streptomycin, and 0.25 μ g/mL amphotericin B]) via pipette delivery. The cell culture assay trays were incubated at 37 \pm 2°C for 7 days in a humidified atmosphere of 5 \pm 1% CO₂ and examined regularly for the presence or absence of unspecified cytopathic effects, cytotoxicity, and contamination. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. Controls included those for cell culture control, cytotoxicity, dried virus plate recovery, and neutralization. The dried virus plate recovery titer obtained for Poliovirus 1, Strain Chat, ATCC VR-1562 was **4.55 log₁₀ TCID₅₀** per carrier. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥ 2.75 log₁₀** for both batches.

Note: Protocol was amended on 20 FEB 2015 to change the test substance expiration date from 01 FEB 2015 to 15 MAR 2015. This expiration date modification regards the date of manufacture as the date of test substance titration to the lower certifiable limit, and presents an expiration date at 30 days past the new date of manufacture.

A protocol deviation from the approved protocol occurred on 19 FEB 2015 wherein Human Poliovirus, Strain Chat, was diluted from its original viral stock vial to a low titer suspension for use in the Neutralization Validation Control. Results recovered on 26 FEB 2015 from this testing demonstrated that the Neutralization Validation Control inoculum titer was above the acceptable level dictated within Protocol P1285. Because neutralization could not be validated this testing was repeated on 03 MAR 2015 with a reduced inoculum titer.

A deviation from the approved protocol occurred on 19 FEB 2015 and 03 MAR 2015 wherein the EcaFlo Anolyte test substance (Lot: 1-2-2015-1; Lot: 1-2-2015-2) was tested while at an active concentration below that listed within the approved protocol (410ppm HOCl). Test Substance Lots 1-2-2015-1 and 1-2-2015-2 were diluted by the Study Sponsor to an active concentration of 409ppm HOCl.

A deviation from the approved protocol occurred on 19 FEB 2015 wherein the Sephacryl @-1000 Super Fine Gel Column containing the harvested Plate Recovery Control for testing against Human Poliovirus 1, Strain Chat, ATCC VR-1462 was run two times through the centrifuge. The second centrifuge exposure was necessitated by the slippage of the column

into the elute during the initial run. This slippage prevented the full volume of elute from being recovered from the column.

According to the Study Director, these three deviations did not impact the integrity or validity of the study.

6. MRID 49680706 “Virucidal Efficacy of a Disinfectant for Use on Nonporous, Inanimate Surfaces – Rhinovirus 16, Strain 11757”, Test Organism: Rhinovirus 16, Strain 11757, ATCC VR-283 for EcaFlo® Anolyte, by Erika Guin, B.S. Study conducted at Antimicrobial Test Laboratories. Study completion date – May 11, 2015. Study Identification No. GLP1258.

This study was conducted against Rhinovirus 16, Strain 11757, ATCC VR-283, using MRC-5 (ATCC CCL-171) as the host cell line. Two batches (3-2-2015-1 and 3-2-2015-2) of the product, EcaFlo® Anolyte, EPA Reg. No. 82341-1, were tested using Protocol No. P1288 (copy provided). The product was received ready to use. Five (5) percent fetal bovine serum was added to the prepared culture to achieve a 5% organic soil load. Two glass petri dishes (one per lot) were inoculated with 0.20 mL of the prepared virus test inoculum (supplemented by the organic soil load) and spread over the entire area. The viral inoculum is allowed to dry for 7 minutes, or until visibly dry, at 26.2-26.3°C and at 20% relative humidity. Each contaminated and dried carrier was treated by pipette delivery of 2.0 mL of the test substance. The carriers are gently rotated to ensure complete coverage of the test substance over the entirety of each test surface. The carriers were exposed for 10 minutes \pm 5 seconds at 26.2°C. After the contact time, sterile cell scrapers are used to mechanically detach the virus films from the glass Petri dish carriers. The suspensions are promptly pipetted into pre-equilibrated Sephacryl (S-1000 SF) Gel Filtration Columns (phosphate-buffered saline [PBS] supplemented with 0.5% fetal bovine serum) for test substance neutralization. The filtrates (10^{-1} dilution) were then tittered by 10-fold serial dilution and applied in quadruplicate per dilution to the host cell culture monolayers prepared to suitable confluency in multi-well trays. All assay trays were incubated at 37 \pm 2°C (5 \pm 1% CO₂), for a minimum of 30 minutes to facilitate virus-host cell adsorption. Each well then received ~1.0mL of the test/cell culture medium (EMEM supplemented with 2% (v/v) fetal bovine serum (FBS) plus antibiotics [100 μ g/mL Kanamycin, 100 units/mL penicillin G, 100 μ g/mL Streptomycin, and 0.25 μ g/mL amphotericin B]) via pipette delivery. The cell culture assay trays were incubated at 37 \pm 2°C for 7 days in a humidified atmosphere of 5 \pm 1% CO₂ and examined regularly for the presence or absence of unspecified cytopathic effects, cytotoxicity, and contamination. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. Controls included those for cell culture control, cytotoxicity, dried virus plate recovery, and neutralization. The dried virus plate recovery titer obtained for Rhinovirus 16, Strain 11757, ATCC VR-283 was **6.30 log₁₀ TCID₅₀** per carrier. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥ 4.50 log₁₀** for both batches.

Note: A deviation from the approved protocol occurred on 06 MAR 2015 wherein the EcaFlo Anolyte test substance (Lot: 3-2-2015-1; Lot: 3-2-2015-2) was tested while at an active concentration below that listed within the approved protocol (410 ppm). Test Substance Lots 3-2-2015-1 and 3-2-2015-2 were diluted by the Study Sponsor on 02 MAR 2015 to the active ingredients of 405 ppm and 408 ppm HOCl, respectively. It is the decision of the Study Director that this deviation did not impact the integrity or validity of the study as evidenced by the deviating concentrations falling below the level dictated by the protocol, rather than above.

7. MRID 49680707 “Virucidal Efficacy of a Disinfectant for Use on Nonporous, Inanimate Surfaces – Human Rotavirus (Group A), Strain Wa”, Test Organism: Human Rotavirus (Group A), Strain Wa (TC-Adapted), ATCC VR-2018 EcaFlo® Anolyte, by Erika Guin, B.S. Study conducted at Antimicrobial Test Laboratories. Study completion date – May 01, 2015. Study Identification No. GLP1253.

This study was conducted against Human Rotavirus (Group A), Strain Wa (TC-Adapted), ATCC VR-2018, using MA-104 (ATCC CCL-2738.1) as the host cell line. Two batches (3-2-2015-1, and 3-2-2015-2) of the product, EcaFlo® Anolyte, EPA Reg. No. 82341-1, were tested using Protocol No. P1283 (copy provided). The product was received ready to use. Five (5) percent fetal bovine serum was added to the prepared culture to achieve a 5% organic soil load. Two glass petri dishes (one per lot) were inoculated with 0.20 mL of the prepared virus test inoculum (supplemented by the organic soil load) and spread over the entire area. The viral inoculum is allowed to dry for 6 minutes, or until visibly dry, at 21.6-21.8°C and at 16-19% relative humidity. Each contaminated and dried carrier was treated by pipette delivery of 2.0 mL of the test substance. The carriers are gently rotated to ensure complete coverage of the test substance over the entirety of each test surface. The carriers were exposed for 10 minutes \pm 5 seconds at 21.8-22.3°C. After the contact time, sterile cell scrapers are used to mechanically detach the virus films from the glass Petri dish carriers. The suspensions are promptly pipetted into pre-equilibrated Sephacryl (S-1000 SF) Gel Filtration Columns (phosphate-buffered saline [PBS] supplemented with 0.5% fetal bovine serum) for test substance neutralization. The filtrates (10^{-1} dilution) were then tittered by 10-fold serial dilution and applied in quadruplicate per dilution to the host cell culture monolayers prepared to suitable confluency in multi-well trays. All assay trays were incubated at 37 \pm 2°C (5 \pm 1% CO₂), for a minimum of 30 minutes to facilitate virus-host cell adsorption. Each well then received ~1.0mL of the test/cell culture medium (EMEM supplemented with 4 μ g/ml Trypsin plus antibiotics [100 μ g/mL Kanamycin, 100 units/mL penicillin G, 100 μ g/mL Streptomycin, and 0.25 μ g/mL amphotericin B]) via pipette delivery. The cell culture assay trays were incubated at 37 \pm 2°C for 7 days in a humidified atmosphere of 5 \pm 1% CO₂ and examined regularly for the presence or absence of unspecified cytopathic effects, cytotoxicity, and contamination. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. Controls included those for cell culture control, cytotoxicity, dried virus plate recovery, and neutralization. The dried virus plate recovery titer obtained for Human Rotavirus (Group A), Strain Wa (TC-Adapted), ATCC VR-2018 was **5.55 log₁₀ TCID₅₀** per carrier. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥ 3.75 log₁₀** for both batches.

Note: The Protocol was amended on 05 MAR 2015 to discontinue the use of EcaFlo Anolyte test substance (Lot: 1-2-2015-1; Lot: 1-2-2015-2) as of 04 MAR 2015. This protocol amendment also indicated that all testing occurring beyond the date of 04 MAR 2015 under study ID GLP1253m guided by Protocol Number P1283, would be performed with EcaFlo Anolyte test substance (Lot: 3-2-2015-1; Lot: 3-2-2015-2), with each new test substance lot having an expiration date of 01 APR 2015.

A deviation from the approved protocol occurred on 06 MAR 2015 wherein the EcaFlo Anolyte test substance (Lot: 3-2-2015-1; Lot: 3-2-2015-2) was tested while at an active concentration below that listed within the approved protocol (410 ppm). Test Substance Lots 3-2-2015-1 and 3-2-2015-2 were diluted by the Study Sponsor on 02 MAR 2015 to the active ingredients of 405 ppm and 408 ppm HOCl, respectively. It is the decision of the Study Director that this deviation did not impact the integrity or validity of the study as evidenced by the deviating concentrations falling below the level dictated by the protocol, rather than above.

Another deviation from the Standard Operating Procedure (TFO 007.1- “Virucidal Efficacy Assay”) occurred on 06 MAR 2015 wherein dilutions of the Plate Recovery Control, Viral

Efficacy Assay (Lot: 3-2-2015-1; Lot: 3-2-2015-2) and additional Neutralization Effectiveness, Cytotoxicity, and Cell Culture controls were plated to 24-well trays containing host cell monolayers created more than 48 hours prior to use. The host cell monolayers were prepared 03 MAR 2015, and evaluated on 05 MAR 2015 for their level of confluence. It was the decision of the Study Director to delay testing until 06 MAR 2015 to allow the host cell cultures to reach an optimal level of confluence for Human Rotavirus (Group A), Strain Wa, ATCC VR-2018 infection.

The third deviation occurred on 20 FEB 2015 wherein the Sephacryl S-1000 Super Fine Gel Column containing the harvested Plate Recovery Control for testing against Human Rotavirus (Group A), Strain Wa, ATCC VR-2018 was run two times through the centrifuge. The second centrifuge exposure was necessitated by the slippage of the column into the elute during the initial run. This slippage prevented the volume of elute from being recovered from the column.

According to the Study Director, these deviations did not impact the integrity or validity of the study.

8. **MRID 48992810 “Fungicidal Use-Dilution Method”, Test Organism: *Candida albicans* (ATCC 10231) EcaFlo® Anolyte, by Nicole Albert. Study conducted at ATS Labs. Study completion date – July 31, 2012. Project Number A13550.

This study was conducted against *Candida albicans* (ATCC 10231). Two lots (Lots 5/30/2012-1 and 5/30/2012-2) of the product, EcaFlo® Anolyte, were tested according to the Official Methods of Analysis, AOAC Use-Dilution Test modified for Fungicides, 2009 ED., using ATS Labs protocol # IET01041112.FUD.3 (copy provided). The product was received as a concentrated solution and per sponsor instruction each lot was diluted to 410 ppm HOCl. For test date 6/12/2012, Lot 5/30/12-1 was prepared using 427 mL of test substance + 72.9 mL sterile deionized water. Lot 5/30/2012-2 was prepared using 430 mL of test substance + 70.3 mL sterile deionized water. Per Sponsor request, Lot 5/30/2012-1 was repeated on July 27, 2012 and was prepared using 130.0 mL of test substance + 9.88 mL of sterile deionized water. Fetal bovine was added to the *Candida albicans* prepared culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed for 15±2 minutes in a suspension of test organism, at a ratio of 1 carrier per 1 mL culture. For test date, 6/21/12, the carriers were dried for 38 minutes at 35-27°C at 67% relative humidity. For test date, 7/27/2012, the carriers were dried for 38 minutes at 35-37°C at 65% relative humidity. Each carrier was placed in 10.0 mL of the use dilution for 10 minutes at 20±1°C. Following exposure, individual carriers were transferred to 10 mL of Sabouraud Dextrose Broth containing 0.1% sodium thiosulfate to neutralize. Carriers were transferred from primary subculture tubes into individual secondary subculture tubes containing 10mL of Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80 ≥30 minutes after subculture of the first carrier. All subcultures and control plates were incubated for 3 days at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for culture purity, organic soil sterility, carrier sterility, neutralizing subculture medium sterility, viability, neutralization confirmation, and carrier population.

Note: Testing was performed on 6/21/12, which resulted in Lot 5/30/2012-1 showing growth of *Candida albicans*. Per Sponsor's request, testing was repeated to confirm the results. On 7/27/12, Lot 5/30/2012-1 was tested against *Candida albicans* and no growth was observed. Results from both test dates are valid and are presented in the body of MRID 489928-10.

**Summary taken from "Secondary Review of Contractor's (Summitec Corporation) Efficacy Review for EcaFlo® Anolyte, EPA Reg. No. 82341-1; DP Barcode: D407169" from March 5, 2013 by Lorilyn Montford.

V. RESULTS

Hard, Non-Porous Surface Virucidal Disinfectant

Contact Time	MRID No.	Organism	Results			Dried Virus Control (TCID ₅₀ /carrier)
			Description	Lot 3-2-2015-1	Lot 3-2-2015-2	
10 minutes	496807-01	Adenovirus 1, Strain Adenoid 71	10 ⁻¹ to 10 ⁻⁶ dilutions	Complete Inactivation	Complete Inactivation	10 ^{5.55}
			TCCD ₅₀ /0.1mL	≤10 ^{0.50}	≤10 ^{0.50}	
			TCCD ₅₀ /carrier	≤10 ^{1.80}	≤10 ^{1.80}	
			Log Reduction	≥3.75	≥3.75	
	496807-06	Rhinovirus 16, Strain 11757	10 ⁻¹ to 10 ⁻⁶ dilutions	Complete Inactivation	Complete Inactivation	10 ^{6.30}
			TCCD ₅₀ /0.1mL	≤10 ^{0.50}	≤10 ^{0.50}	
			TCCD ₅₀ /carrier	≤10 ^{1.80}	≤10 ^{1.80}	
			Log Reduction	≥4.50	≥4.50	
	496807-07	Human Rotavirus (Group A), Strain Wa	10 ⁻¹ to 10 ⁻⁶ dilutions	Complete Inactivation	Complete Inactivation	10 ^{5.55}
			TCCD ₅₀ /0.1mL	≤10 ^{0.50}	≤10 ^{0.50}	
			TCCD ₅₀ /carrier	≤10 ^{1.80}	≤10 ^{1.80}	
			Log Reduction	≥3.75	≥3.75	
			Description	Lot 1-2-2015-1	Lot 1-2-2015-2	
	496807-02	Enterovirus 68, Strain Fermon	10 ⁻¹ to 10 ⁻⁶ dilutions	Complete Inactivation	Complete Inactivation	10 ^{4.55}
			TCCD ₅₀ /0.1mL	≤10 ^{0.50}	≤10 ^{0.50}	
			TCCD ₅₀ /carrier	≤10 ^{1.80}	≤10 ^{1.80}	
			Log Reduction	≥2.75	≥2.75	
	496807-03	Feline Calicivirus, Strain F-9	10 ⁻¹ to 10 ⁻⁶ dilutions	Complete Inactivation	Complete Inactivation	10 ^{4.80}
			TCCD ₅₀ /0.1mL	≤10 ^{0.50}	≤10 ^{0.50}	
			TCCD ₅₀ /carrier	≤10 ^{1.80}	≤10 ^{1.80}	
			Log Reduction	≥3.00	≥3.00	
	496807-04	Human Respiratory Syncytial Virus, Strain A-2	10 ⁻¹ to 10 ⁻⁶ dilutions	Complete Inactivation	Complete Inactivation	10 ^{5.30}
			TCCD ₅₀ /0.1mL	≤10 ^{0.50}	≤10 ^{0.50}	
			TCCD ₅₀ /carrier	≤10 ^{1.80}	≤10 ^{1.80}	
			Log Reduction	≥3.50	≥3.50	
	496807-05	Poliovirus 1, Strain Chat	10 ⁻¹ to 10 ⁻⁶ dilutions	Complete Inactivation	Complete Inactivation	10 ^{4.55}
			TCCD ₅₀ /0.1mL	≤10 ^{0.50}	≤10 ^{0.50}	
			TCCD ₅₀ /carrier	≤10 ^{1.80}	≤10 ^{1.80}	
			Log Reduction	≥2.75	≥2.75	

****Hard, Non-Porous Surface Fungicidal Disinfectant**

Contact Time	MRID No.	Organism	No. Exhibiting Growth/Total No. Tested		Carrier Population (CFU/carrier)
			Lot 5/30/2012-1	Lot 5/30/2012-2	
10-Minute Exposure Time at 410 ppm HOCl	489928-10	<i>Candida albicans</i> (ATCC 10231)	1° = 0/10 2° = 2/10	1° = 0/10 2° = 0/10	7.1 x 10 ⁶
			1° = 0/10* 2° = 0/10		2.0 x 10 ⁵

*Testing of Lot 5/30/2012-1 was repeated.

**Table taken from "Secondary Review of Contractor's (Summitec Corporation) Efficacy Review for EcaFlo® Anolyte, EPA Reg. No. 82341-1; DP Barcode: D407169" from March 5, 2013 by Lorilyn Montford.

VI. CONCLUSIONS

Note: Registrant requests for a reconsideration of the *Candida albicans* study (MRID 489928-10). The registrant's justification for the repeat testing was that the high carrier populations of 6/21/12 contributed to the growth in 2 of the 10 secondary subculture tubes. According to Agency's guidelines, this reason is valid for a reconsideration.

1. The submitted efficacy data **support** the use of the product, EcaFlo® Anolyte (EPA Reg. No. 82341-1), as a ready to use disinfectant with virucidal activity against the viral strains listed below on hard, non-porous surfaces in a 10 minute contact time in the presence of and 5% organic soil load.

MRID 496807-01 Adenovirus 1, Strain Adenoid 71, ATCC VR-1
 MRID 496807-03 Feline Calicivirus, Strain F-9, ATCC VR-782
 MRID 496807-04 Human Respiratory Syncytial Virus, Strain A-2, ATCC VR-1540
 MRID 496807-06 Rhinovirus 16, Strain 11757, ATCC VR-283
 MRID 496807-07 Human Rotavirus (Group A), Strain Wa, ATCC VR-2018

Recoverable virus titer of at least 4 log₁₀ were achieved. Complete inactivation (no growth) was demonstrated in all dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

2. The submitted efficacy data **do not support** the use of the product, EcaFlo® Anolyte (EPA Reg. No. 82341-1), as a ready to use disinfectant with virucidal activity against the viral strains listed below on hard, non-porous surfaces in a 10 minute contact time in the presence of and 5% organic soil load.

MRID 496807-02 Enterovirus 68, Strain Fermon, ATCC VR-561
 MRID 496807-05 Poliovirus 1, Strain Chat, ATCC VR-1562

Recoverable virus titer of at least 4 log₁₀ were achieved. Complete inactivation (no growth) was demonstrated in all dilutions tested. When cytotoxicity is evident, at least a 3-log reduction in titer was not demonstrated beyond the cytotoxic level.

3. The submitted efficacy data **support** the use of the product, EcaFlo® Anolyte (EPA Reg. No. 82341-1) at a dilution of 410 ppm HOCl (with sterile deionized water) as a disinfectant with fungicidal activity against the following organisms on hard, non-porous surfaces in a 10 minute contact time in the presence of 5% organic soil load.

MRID 489928-10 *Candida albicans* (ATCC 10231)

Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

VII. LABEL RECOMMENDATIONS

1. The proposed label claims are acceptable regarding the use of the product, EcaFlo® Anolyte at 500 ppm FAC, as a ready to use disinfectant against the following microorganisms on hard, non-porous surfaces for a 10 minute contact time:

Adenovirus 1, Strain 71, ATCC VR-1
Norovirus or Norwalk Virus (as Feline Calicivirus, Strain F-9, ATCC VR-782)
Respiratory Syncytial Virus, Strain A-2, ATCC VR-1540
Rhinovirus 16, Strain 11757, ATCC VR-283
Rotavirus (Group A), Strain Wa, ATCC VR-2018

These claims **are supported** by the applicant's data.

2. The proposed data are acceptable regarding the use of the product, EcaFlo® Anolyte at 500 ppm FAC, as a ready to use disinfectant with fungicidal activity against the following organisms on hard, non-porous surfaces for a 10 minute contact time:

Candida albicans (ATCC 10231)

This claim **is supported** by the applicant's data.

The following revisions must be made to the proposed label:

3. The proposed label claims are not acceptable regarding the use of the product, EcaFlo® Anolyte at 500 ppm FAC, as a ready to use disinfectant against the following microorganisms on hard, non-porous surfaces for a 10 minute contact time:

Enterovirus 68, Strain Fermon, ATCC VR-561
Poliovirus 1, Strain Chat, ATCC-VR1562

These claims **are not supported** by the applicant's data. The applicant must remove these claims from the proposed label.

4. On page 2 of the proposed label, applicant must remove the claim “Hypochlorous acid (HOCL or HClO) kills bacteria, viruses, mold, fungi, and spores,” since this is a misleading statement.

5. On page 2 of the proposed label, applicant must remove the following paragraphs from the label:

“The properties of **EcaFlo® Anolyte** can be precisely controlled by manipulating power to the electrolytic cell, brine flow rate through the cell and the conductivity of the brine in the cell. Anolyte can be applied as a *liquid or spray*.”

EcaFlo® Anolyte freezes at 32° F and boils at 212° F. Anolyte is a colorless, aqueous solution, with a slight chlorine or ozone odor. After production, **EcaFlo® Anolyte** must be stored in a closed, plastic container in a cool, dark area away from direct sunlight. Anolyte is intended to be used soon after being produced. The Anolyte product must be used within 30 days of production for disinfection applications or may be used after 30 days for sanitizing, deodorizing, and cleaning applications when diluted and tested with chlorine test kit or chlorine test strips to adjust to desired chlorine level.”

6. On page 5 of the proposed label, the applicant must remove the section titled “**MOLD AND MILDEW CONTROL APPLICATIONS**”. Data were not generated for this claim. The microorganism, *Aspergillus niger*, has been selected by the Agency for this type of testing.

7. On page 5 of the proposed label, the applicant must revise to remove “**Disinfect**” from the sub section titled “[**To**] **Clean, Disinfect, and Deodorize Toilet Bowls – and/or – Urinals – and/or – Bidets**” under the section “**GENERAL CLEANING AND DEODORIZING DIRECTIONS**”. Testing was not conducted according to the OCSPP 810.2200 Guidelines pertaining to disinfectants for internal toilet and urinal bowl surfaces above and below the water line. The use of the contained bowl water (96 fl. oz. of 200-400 ppm hard water or lower volume for low volume toilets) is required to calculate the appropriate use dilution for testing.

8. On page 7 of the proposed label, applicant must remove the following phrases from the first paragraph under the section “**SANITIZING APPLICATIONS**”: “...that kills bacteria that may cause food poisoning” (Agency does not allow statements that imply or suggest that the product can or will prevent or control disease or offer health protection) and “... not always requiring a rinse”. In the same paragraph, applicant must insert, “hard non-porous” before the word “surfaces”.

9. On page 7 of the proposed label, applicant must remove “[on dirty surfaces]” at the end of the second paragraph of the page, which claimed “This product kills 99.9% of the bacteria [on dirty surfaces]”. The “dirty surfaces” need to be clarified. A heavily soiled area requires a preliminary cleaning step.

10. All references to the use of chlorine test strips must be made optional (i.e. under instructions [**To**] [**Clean and**] **Sanitize Water Sensitive [Electronic] Equipment, [Hard, Non-Porous] Surfaces** on page 7).

11. On page 7 of the proposed label, under “**Hard, Non-Porous Food Contact Surfaces**”, applicant must remove the language “This product exceeds AOAC international Chlorine (Available) in Disinfectant Germicidal Equivalent Concentration...” The word “exceeds” in this context is misleading and not allowed by Agency.

12. On page 7 of the proposed label, applicant must remove the claim “... against gram positive and gram negative bacteria...” These claims imply a greater range of effectiveness than that supported by data.

13. On the proposed label, applicant must remove “[maximum 200 ppm FAC]” from the use-directions on pages 8 and 9, because this claim implies that any concentrations below 200 ppm FAC would be efficacious against the microorganisms.

14. Applicant must always use an asterisk to reference specific viruses whenever the terms “viruses”, “virucide” or “virucidal” are used in the label. Asterisks are required to indicate that there

is clarifying language elsewhere on the label that describes the type of viruses the product is efficacious against.

15. On page 10 of the proposed label, the applicant must remove the last part (“...with suspected or confirmed Ebola virus infection”) from the claim, “Meets [U.S] EPA and [U.S.] CDC [recommended] criteria – and/or – guidance for using an EPA-registered hospital disinfectant with label claims for non-enveloped viruses (e.g. norovirus, rotavirus, adenovirus, poliovirus) to disinfect environmental surfaces with suspected or confirmed Ebola virus infection”. Agency does not allow product label to specifically mention effectiveness against the Ebola virus. Instead, label can mention effectiveness against a different virus such as norovirus, rotavirus, adenovirus, and/or poliovirus (with supported data). Please consult Agency’s link below for information on emerging pathogens.

<http://www2.epa.gov/pesticide-registration/list-l-disinfectants-use-against-ebola-virus>

16. On page 10 of the proposed label, applicant must remove “poliovirus” from the claim, “Meets [U.S] EPA and [U.S.] CDC [recommended] criteria – and/or – guidance for using an EPA-registered hospital disinfectant with label claims for non-enveloped viruses (e.g. norovirus, rotavirus, adenovirus, poliovirus) to disinfect environmental surfaces with suspected or confirmed Ebola virus infection”. Data did not confirm effectiveness against poliovirus.

17. On page 10 of the proposed label, applicant must remove the claims “kills multiple drug resistant bacterium” and “kills a wide range of bacteria”. These claims imply a greater range of effectiveness than that supported by data.

18. On page 10 of the proposed label, applicant must remove “poliovirus” from the claim, “Effective against non-enveloped viruses [(such as – or – e.g.,) [(] [norovirus], [rotavirus], [adenovirus], [poliovirus] ...” Data did not confirm effectiveness against poliovirus.

19. On page 11 of the proposed label, applicant must remove the claim “...are used to disinfect environmental surfaces in rooms of patients with infectious diseases” at the top of the page. Agency does not allow statements that imply or suggest that the product can or will prevent or control disease or offer health protection.

20. On page 11 of the proposed label, applicant must remove the claim against “biofilm(s)”. Product was not tested for effectiveness against biofilms. Applicant must also remove “Fast acting disinfectant” as a claim. A contact time of 10 minutes for disinfectant is not considered fast-acting by Agency.

21. On page 11 of the proposed label, applicant must remove the word “exposure” from the claim “Reduces exposure to Clostridium difficile...” The word “exposure” in this context is misleading and not allowed by Agency.

22. On page 11 of the proposed label, applicant must remove the terms “Fights”, “Stops” and “Prevents” from the claim “Fight(s) – and/or – Stops – and/or – Prevent(s) cross-contamination between treated hard, non-porous surfaces”. This implied claim of heightened efficacy of the product is not allowed by Agency.

23. On page 11 of the proposed label, applicant must add “... between treated hard, non-porous surfaces” after the claim “Can help reduce risk of cross contamination”.

24. On page 12 of the proposed label, the applicant must remove the word “airborne” from the following claims: “Kills – or – Effective against [airborne] bacteria”, “Kills – or – Effective against [airborne] viruses” and “Kills – or – Effective against airborne pathogens”. The product was not designed as an aerosol product.

25. On page 12 of the proposed label, applicant must remove the claim “[Simply] Spray and walk away”.

26. On page 12 of the proposed label, the applicant must remove the words “[green]” and “germ pollution” from the claim “The [easy] [green] [simple] solution to germ pollution”.

27. On page 12 of the proposed label, applicant must remove the word “controls” from the claim “This product controls cross-contamination between treated hard, non-porous surfaces”.

28. On page 15 of the proposed label, applicant must specify the category “SURFACES” (i.e. HARD, NON-POROUS SURFACES).

29. On page 15 of the proposed label, the applicant must remove “Carpets” as a surface claim. The product is designed for use on hard, non-porous surfaces.

30. On page 15 of the proposed label, applicant must remove “or – Air Vent” in the claim “Exterior Surfaces of Air Vents – or – Air Vent”; “Exterior Surfaces of Air Vents” is appropriate.

31. On page 15 of the proposed label, applicant must remove “- or – Medical Equipment Surfaces” from the claim, “External Surfaces of Medical Equipment – or – Medical Equipment Surfaces”; “External Surfaces of Medical Equipment” is appropriate.

32. On page 16 of the proposed label, applicant must revise to add “Plastic/Non-Porous” to the claim “Mattress Covers”.

33. On page 16 of the proposed label, applicant must revise to add “Exterior surfaces of” to the claim “Toilets”. Product was not tested as a disinfectant for internal toilet and urinal bowl surfaces.

34. On page 16 of the proposed label, applicant must revise to add “Exterior surfaces of” to the claim “Ultrasound Transducers [and Probes]”.

35. On page 16 of the proposed label, applicant must revise to add “Exterior surfaces of” to the claim “Ventilators”.

36. On page 17 of the proposed label, applicant must specify the category “SURFACES” (i.e. HARD, NON-POROUS SURFACES).

37. On page 19 of the proposed label, applicant must specify the category “SURFACES” (i.e. HARD, NON-POROUS SURFACES).

38. On page 20 of the proposed label, applicant must remove the claim, “Misting systems”, provide special use directions in the label to disinfect the systems, or specify the use of the product on the exterior surfaces of these systems. The same applies to page 24 with the claim “Vaporizers”.

39. On page 21 of the proposed label, applicant must remove the claim, "Heating, Ventilation, and Air-Conditioning (HVAC) systems", unless product testing is performed and special use-directions are added to the label to disinfect the interior hard, non-porous surfaces of HVAC systems.

40. On page 22 on the proposed label, applicant must specify the category "SURFACES" (i.e. HARD, NON-POROUS SURFACES).

41. On page 22 of the proposed label, applicant must revise to add "Exterior surfaces of" to the claim, "[Air] Vents".

42. On page 23 of the proposed label, applicant must remove the claim, "Carpets". The product is designed for use on hard, non-porous surfaces.

43. On page 23 of the proposed label, applicant must revise to indicate the surfaces of the claim "Drains".